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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JANSSEN PHARMACEUTICA N.V. and JANSSEN PHARMACEUTICA PRODUCTS, L.P., Plaintiffs, v. APOTEX INC., Defendant.	Civil Action No. 06-1020 (JCL) **ANSWER, DEFENSES, COUNTERCLAIMS, AND DEMAND FOR JURY TRIAL OF DEFENDANT APOTEX INC.**

Defendant Apotex Inc. ("Apotex"), by way of its Answer to the Complaint for Patent Infringement of Plaintiffs Janssen Pharmaceutica N.V. and Janssen Pharmaceutica Products, L.P. ("Plaintiffs"), says:

The Parties

1. On information and belief, Apotex admits the allegations of Paragraph 1.

2. On information and belief, Apotex admits the allegations of Paragraph 2.

3. Apotex admits the allegations in the first sentence of Paragraph 3. Apotex denies the remaining allegations of Paragraph 3.

Jurisdiction and Venue

4. Paragraph 4 contains legal conclusions to which no answer is required. To the extent an answer is required, Apotex admits that this action purports to arise under the patent laws of the United States, and that subject matter jurisdiction is proper. Apotex denies the remaining allegations of Paragraph 4.

5. Paragraph 5 contains legal conclusions to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 5.

6. Paragraph 6 contains legal conclusions to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 6.

Count I: Patent Infringement

7. Apotex restates and incorporates by reference its responses to the allegations of the foregoing Paragraphs 1-6 as though fully set forth herein.

8. Apotex admits that on or about February 14, 1989, the United States Patent and Trademark Office issued U.S. Patent No. 4,804,663 ("the '663 patent"), entitled "3-PIPERIDINYL-SUBSTITUTED 1,2-BENZISOXAZOLES AND 1,2-BENZISOTHIAZOLES," but denies that the '663 patent is valid or enforceable. Apotex admits that a copy of the '663 patent is attached to Plaintiffs' Complaint as Exhibit A.

9. Apotex is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 9, and therefore denies such allegations.

10. Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer is required, Apotex admits that the U.S. Food and Drug Administration ("FDA") publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), identifies "Janssen Pharma" as the holder of New Drug Application ("NDA") No. 20-588, approved June 10, 1996, for Risperdal® (risperidone) Oral Solution 1 mg/mL, and that Janssen had the FDA list the '663 patent in the Orange Book in connection with NDA No. 20-588. Apotex denies the remaining allegations of Paragraph 10.

11. Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer is required, Apotex admits only that Janssen had the FDA list the '663 patent in FDA's Orange Book in connection with NDA No. 20-588 for Risperdal® (risperidone) Oral Solution 1 mg/mL. Apotex denies the remaining allegations of Paragraph 11.

12. Apotex is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 12, and therefore denies such allegations.

13. Admitted.

14. Admitted.

15. Admitted.

16. Apotex admits that it has filed with FDA a so-called "Paragraph IV Certification," pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), to the '663 patent stating that such patent is invalid, unenforceable and/or not infringed by the proposed risperidone oral solution drug product that is the subject of Apotex's ANDA No. 77-719. Apotex denies the remaining allegations of Paragraph 16.

17. Apotex admits that it sent written notice of its ANDA No. 77-719 and Paragraph IV Certification to the '663 patent to Plaintiffs in a letter dated January 26, 2006; that such notice included the detailed factual and legal basis for Apotex's certification that the '663 patent is invalid, unenforceable and/or not infringed by Apotex's proposed risperidone oral solution drug product; that such notice satisfied all statutory and regulatory requirements; and that a copy of such notice is attached to the Complaint as Exhibit B. Apotex is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 17, and therefore denies all such allegations.

18. Apotex admits that Apotex Inc. submitted ANDA No. 77-719 to FDA.

19. Apotex admits that it sent written notice of its ANDA No. 77-719 and Paragraph IV Certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), to the '663 patent to Plaintiffs in a letter dated January 26, 2006; that such notice included the detailed factual and legal basis for Apotex's certification that the '663 patent is invalid, unenforceable, and/or not infringed by Apotex's proposed risperidone oral solution drug product; and that such notice satisfied all statutory and regulatory requirements. Apotex denies the remaining allegations of Paragraph 19.

20. Denied.

21. Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is required, Apotex admits that it was aware of the existence of the '663 patent prior to filing ANDA No. 77-719. Apotex denies the remaining allegations of Paragraph 21.

22. Denied.

Count II: Declaratory Judgment of Patent Infringement

23. Apotex restates and incorporates by reference its responses to the allegations of the foregoing paragraphs 1-22 as though fully set forth herein.

24. Apotex admits that it has submitted to FDA an ANDA (No. 77-719), which contains a Paragraph IV Certification to the '663 patent, for the purpose of engaging in the commercial manufacture, use, and sale of risperidone oral solution 1 mg/1mL before the expiration of such patent. Apotex denies the remaining allegations of Paragraph 24.

25. Denied.

26. Paragraph 26 contains legal conclusions to which no answer is required. To the extent an answer is required, Apotex admits only that it has submitted to FDA an ANDA (No. 77-719) for risperidone oral solution 1 mg/1mL. Apotex denies the remaining allegations of Paragraph 26.

27. Apotex admits that there is an actual and continuing controversy between Plaintiffs and Apotex regarding the infringement, validity and enforceability of the '663 patent. Apotex denies the remaining allegations of Paragraph 27.

Prayer For Relief

Apotex denies that Plaintiffs are entitled to any of the relief requested in paragraphs (A) through (G) of the Complaint, or to any relief whatsoever. Apotex respectfully requests that the Court: (a) dismiss the Complaint with prejudice; (b) enter judgment in favor of Apotex; (c) award Apotex the reasonable attorneys' fees and costs of defending this action pursuant to 35 U.S.C. § 285; and (d) award Apotex such further relief as the Court deems just and appropriate. Apotex further denies each allegation not specifically admitted herein.

DEFENSES

Without undertaking any of the burdens imposed by law on Plaintiffs, and without admitting any of the allegations in the Complaint not otherwise admitted, Apotex asserts the following defenses:

First Defense

The manufacture, use, sale, offer for sale, or importation of the risperidone oral solution drug product that is the subject of Apotex's ANDA No. 77-719 has not infringed, does not infringe, and would not, if made, imported, or marketed, infringe any valid and/or enforceable claim of U.S. Patent No. 4,804,663 ("the '663 patent").

Second Defense

The claims of the '663 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Patent Code.

Third Defense

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

Defendant/Counterclaim-Plaintiff, Apotex Inc. ("Apotex"), by way of Counterclaim against Plaintiffs/Counterclaim-Defendants Janssen Pharmaceutica N.V. and Janssen Pharmaceutica Products, L.P. (collectively, "Plaintiffs/Counterclaim-Defendants" or "Janssen"), states:

The Parties

1. Defendant/Counterclaim-Plaintiff Apotex is a corporation duly organized and existing under the laws of Canada, having a place of business at 150 Signet Drive, Toronto, Canada M9L 1T9.

2. On information and belief, Plaintiff/Counterclaim-Defendant Janssen Pharmaceutica N.V. purports to be a corporation organized and existing under the laws of Belgium having its principal place of business at Turnhoutseweg 30, B-2340 Beerse, Belgium.

3. On information and belief, Plaintiff/Counterclaim-Defendant Janssen Pharmaceutica Products, L.P. purports to be a corporation organized and existing under the laws of the State of Pennsylvania having its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

Jurisdiction And Venue

4. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified at 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5)) ("the MMA").

5. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Janssen because Janssen has availed itself of the rights and privileges of this forum by suing Apotex in this District, and because Janssen conducts substantial business in, and has regular and systematic contact with, this District.

7. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

Background Allegations Common To All Counts

I. Statutory Scheme For Approval Of New And Generic Drugs.

8. The approval of new and generic drugs is governed by the applicable provisions of the Federal Food, Drug, and Cosmetic Act (the "FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No.

98-417, 98 Stat. 1585 (1984) (commonly known as the "Hatch-Waxman Amendments" or "Hatch-Waxman"), and the MMA.

A. New drugs and patent listing requirements.

9. Before marketing a new or previously unapproved drug (*i.e.*, not a generic drug) in the United States, the FFDCA, as amended by Hatch-Waxman and the MMA, requires that an applicant submit, and that FDA approve, a new drug application ("NDA") under 21 U.S.C. § 355(b). The NDA must include, *inter alia*, technical data on the composition of the drug, the means for manufacturing it, clinical trial results to establish the safety and efficacy of the drug, and labeling relating to the use of the drug for which approval is requested.

10. An NDA applicant is required, within its NDA, to submit information (*e.g.*, the patent number and expiration date) for each patent that claims the drug or method of using the drug that is the subject of the NDA and for which a claim of patent infringement could be reasonably asserted if a person not licensed by the patent owner engaged in the manufacture, use, or sale of the drug. 21 U.S.C. § 355(b)(1).

11. FDA publishes patent information submitted by an NDA-holder in the Patent and Exclusivity Information Addendum of FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book").

12. By filing an NDA and submitting a patent for listing in the Orange Book, the NDA-holder/patent owner, by law, represents under penalty of perjury that the listed patent claims the approved NDA drug, or an approved method of using such drug, and that an infringement suit could reasonably be asserted against anyone who engages in the manufacture, use, or sale of the drug, and in particular against any company that is seeking to make a generic version of the NDA drug.

13. The NDA-holder/patent owner necessarily puts all prospective generic ANDA applicants on notice that a suit for infringement can and will be asserted against any ANDA applicant that attempts to seek approval for and market a competing generic version of the NDA drug.

14. Such conduct by the NDA-holder/patent owner gives rise to a reasonable apprehension on the generic ANDA applicant's part that it will face an infringement suit or the threat of one if it attempts to seek approval for or to market a generic version of the NDA drug.

B. Generic drugs and patent certification requirements.

15. The FFDCA, as amended by Hatch-Waxman and the MMA, provides for an ANDA approval process that enables generic pharmaceutical manufacturers to obtain regulatory approval of lower-priced generic versions of previously approved brand-name or NDA drugs on an expedited basis, thereby benefiting the U.S. health-care system and American consumers. The ANDA process is a streamlined version of the full NDA procedure and results in a generic drug product that is normally marketed under the chemical name of the active drug ingredient (*e.g.*, risperidone).

16. An applicant may invoke this procedure for expedited FDA approval of a generic version of an already-approved NDA drug by submitting an ANDA to FDA under 21 U.S.C. § 355(j).

17. Instead of repeating the comprehensive, extensive clinical studies of safety and efficacy conducted for the previously-approved NDA drug, a generic applicant submitting an ANDA is required to establish, among other things, that its generic drug is bioequivalent to the already-approved NDA drug (*i.e.*, has no significant difference in rate and extent of absorption), and that it has the same active ingredient, dosage form, dosage strength, route of administration,

and labeling (with certain exceptions) as the approved NDA drug. 21 U.S.C. § 355(j)(2)(A).

18. An ANDA applicant also is required to address each patent properly listed in the Orange Book in connection with the approved NDA drug. In particular, an ANDA applicant generally must submit one of four types of patent certifications for each listed patent: (I) that the NDA-holder/patent owner has not submitted any patent information to FDA; (II) that the listed patent has expired; (III) that the patent will expire on a future date, and that the generic applicant will not market its drug product until after the expiration date (commonly referred to as a "paragraph III certification"); or, (IV) that the listed patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted (commonly referred to as a "paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV). This last type of certification, a paragraph IV certification, signifies that the generic ANDA applicant intends to market its generic drug prior to expiration of the subject patent.

19. When an ANDA applicant submits a paragraph IV certification for a listed patent, as Apotex did here, the generic applicant must notify the NDA-holder/patent owner that it has filed an ANDA to obtain regulatory approval of a generic version of the NDA drug, and that the ANDA contains a paragraph IV certification for a listed patent (indicating that the ANDA applicant intends to market its generic product before expiration of the listed patent). 21 U.S.C. § 355(j)(2)(B). This notice must contain a detailed statement of the factual and legal basis for the ANDA applicant's paragraph IV certification that the listed patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the ANDA applicant's generic

drug product. 21 U.S.C. § 355(j)(2)(B)(ii). The submission of a paragraph IV certification has two important effects.

C. 180-day exclusivity.

20. First, a generic applicant that is first to submit an ANDA containing a paragraph IV certification for a listed patent is entitled to 180 days of generic market exclusivity during which no other competing generic drug products may be marketed. 21 U.S.C. § 355(j)(5)(B)(iv). This statutory benefit is commonly known as "180-day exclusivity."

21. In particular, § 355(j)(5)(B)(iv) of the FFDCA provides that "[i]f the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection [containing] such a certification, the application shall be made effective not earlier than one hundred and eighty days after" the earlier of: (a) the first commercial marketing of that ANDA applicant's proposed drug; or, (b) any court decision—whether it involves the first applicant or not—that the particular patent that is the subject of the paragraph IV certification is invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iv).

D. Artificial act of infringement.

22. Second, the submission of a paragraph IV certification for a listed patent constitutes a statutory act of infringement that creates the necessary case or controversy and subject matter jurisdiction to enable an NDA-holder/patent owner to file, and a district court to resolve, an action for patent infringement—before the generic drug is actually made, used, or sold—to determine whether the generic drug, if marketed and sold in accordance with the ANDA, would infringe the relevant patent.

23. The submission of an ANDA with a paragraph IV certification creates the necessary case or controversy and subject matter jurisdiction for an ANDA applicant to file a declaratory judgment action against the NDA-holder/patent owner if the ANDA applicant is not sued within the applicable 45-day period, as set forth below.

24. Upon receiving notice of a paragraph IV certification for a listed patent submitted by an ANDA applicant, the NDA-holder/patent owner may file suit for infringement of the listed patent under 35 U.S.C. § 271(e)(2)(A). If such a suit is filed within 45 days of receiving such notification, FDA will delay issuing final approval of the ANDA for up to thirty (30) months. 21 U.S.C. § 355(j)(5)(B)(iii).

25. An NDA-holder/patent owner is not precluded from suing after expiration of the 45-day period. In fact, NDA-holders/patent owners can and often do file suit after expiration of the 45-day period.

26. If the NDA-holder/patent owner does not file such a suit within the 45-day period, the ANDA applicant can file and maintain a suit for declaratory judgment against the NDA-holder/patent owner to obtain patent certainty in the form of a judicial declaration of patent non-infringement and/or invalidity.

E. Congress explicitly mandated that an ANDA applicant may file and maintain a declaratory judgment action when it is not sued.

27. Under the MMA, an ANDA applicant who has filed a paragraph IV certification is statutorily entitled to file and maintain an action for declaratory judgment against an NDA-holder/patent owner if: (a) the 45-day period has passed since notice of the paragraph IV certification was received; (b) neither the patent owner nor the NDA-holder brought an action for infringement of the patent within the 45-day period; and, (c) the NDA-holder/patent owner has

been granted an Offer of Confidential Access to the ANDA. 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa-cc), as amended.

28. Once these three conditions are met, the MMA specifically and unequivocally provides that an ANDA applicant "may, in accordance with section 2201 of title 28, United States Code, bring a civil action under such section against the owner or holder referred to in such subclause . . . for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval . . . ." 21 U.S.C. § 355(j)(5)(C)(i)(II), as amended.

29. An ANDA applicant may exercise its right to file and maintain a declaratory judgment action under the MMA regardless of whether or not the Offer of Confidential Access is accepted. The MMA's declaratory judgment provision applies to all ANDAs pending on or after December 8, 2003, which includes these proceedings. *See* § 1102 of the MMA, 117 Stat. 2066, 2456.

II. Janssen's Risperdal® (Risperidone) Oral Solution NDA.

30. Janssen holds approved NDA No. 20-588 for risperidone oral solution 1 mg/mL, which Janssen markets and sells under the brand-name Risperdal® for the treatment of schizophrenia and bipolar mania.

31. Janssen purportedly began selling risperidone oral solution in or about June 1996, and even today Janssen's brand-name products are the only risperidone drug products available to American consumers. Janssen's 2005 sales for its various risperidone products totaled $3.6 billion (USD).

III. Patents-In-Suit.

32. Janssen purports and claims to own a number of United States patents relating to risperidone, with which Janssen seeks to protect and preserve its lucrative risperidone monopoly from lower-priced generic competition.

33. On or about February 14, 1989, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 4,804,663 ("the '663 patent"), entitled "3-PIPERIDINYL-SUBSTITUTED 1,2-BENZISOXAZOLES AND 1,2-BENZISOTHIAZOLES," to Ludo E. J. Kennis and Jan Vandenberk. According to Janssen, the '663 patent purportedly expires on or about December 29, 2007. A true and correct copy of the '663 patent is attached to this Counterclaim as Exhibit A.

34. On or about September 26, 1995, the PTO issued U.S. Patent No. 5,453,425 ("the '425 patent"), entitled "RISPERIDONE ORAL FORMULATION," to Marc K. J. François and Willy M. A. C. Dries. According to Janssen, the '425 patent purportedly expires on or about July 11, 2014. A true and correct copy of the '425 patent is attached to this Counterclaim as Exhibit B.

35. On or about April 1, 1997, the PTO issued U.S. Patent No. 5,616,587 ("the '587 patent"), entitled "AQUEOUS RISPERIDONE FORMULATIONS," to Marc K. J. François and Willy M. A. C. Dries. According to Janssen, the '587 patent purportedly expires on or about July 11, 2014. A true and correct copy of the '587 patent is attached to this Counterclaim as Exhibit C.

36. Janssen purports and claims to own, and to have the right to enforce, the '663, '425, and '587 patents.

37. On information and belief, Janssen submitted information on the '663, '425, and '587 patents to FDA for listing in the Orange Book in connection with approved NDA No. 20-588 for Risperdal® (risperidone) Oral Solution 1 mg/mL.

38. On information and belief, Janssen certified and declared to FDA that the '663, '425, and '587 patents claim risperidone oral solution, or a method of using risperidone oral solution, and that a claim for patent infringement could be reasonably asserted against any ANDA applicant that attempts to seek approval for, and market, a generic version of risperidone oral solution. By virtue of that submission, FDA listed the '663, '425, and '587 patents in the Orange Book in connection with Janssen's approved NDA No. 20-588 for Risperdal® (risperidone) Oral Solution 1 mg/mL.

39. By listing the '663, '425, and '587 patents in the Orange Book, Janssen maintains, and has affirmatively represented, that such patents claim risperidone oral solution, or a method of using risperidone oral solution, and that an infringement suit could reasonably be asserted against any ANDA applicant, including Apotex, that attempts to seek approval for, and market, a generic version of risperidone oral solution.

40. The listing of the '663, '425, and '587 patents in the Orange Book creates a reasonable apprehension in an ANDA applicant submitting a paragraph IV certification that it will be sued by Janssen for infringement.

41. The listing of the '663, '425, and '587 patents in the Orange Book objectively creates the necessary case or controversy and subject matter jurisdiction for an ANDA-filer to file and maintain a declaratory judgment action.

IV. Apotex's ANDA For Risperidone Oral Solution.

42. Apotex, which is not licensed by the owner of the '663, '425, and '587 patents, submitted ANDA No. 77-719 to FDA seeking approval to manufacture, use, and sell generic risperidone oral solution 1 mg/mL prior to the expiration of such patents.

43. Apotex devoted years and substantial resources to the research, development and testing of its generic risperidone drug product, all toward compiling the information necessary to submit an ANDA for generic risperidone oral solution.

44. As part of its ANDA No. 77-719, Apotex addressed the listed patents for Risperdal® (risperidone) Oral Solution 1 mg/mL. In particular, Apotex's ANDA contains paragraph IV certifications, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), to the '663, '425, and '587 patents, stating that such patents are invalid, unenforceable, and/or not infringed by Apotex's proposed risperidone oral solution drug product. This certification signifies that Apotex intends to market and commercialize its generic risperidone drug product prior to expiration of the '663, '425, and '587 patents.

45. Apotex's risperidone ANDA is substantially complete and was accepted for filing by FDA. Apotex has satisfied all substantive requirements for approval of its generic risperidone drug product. Apotex intends, and is prepared, to market its generic risperidone drug product before expiration of the '663, '425, and '587 patents.

46. The submission of Apotex's Paragraph IV ANDA constitutes a statutory act of infringement under 35 U.S.C. § 271(e)(2)(A) that vests this Court with subject matter jurisdiction to resolve any dispute regarding the infringement or validity of the '663, '425, and '587 patents.

47. In accordance with 21 U.S.C. § 355(j)(2)(B)(i-ii), Apotex provided Janssen with notices of its ANDA and paragraph IV certification to the '663, '425, and '587 patents. These

notices included a detailed statement setting forth the factual and legal bases why the '663, '425, and '587 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Apotex's generic risperidone oral solution. With the notices of its paragraph IV ANDA, as required under 21 U.S.C. § 355(j)(5)(C)(i), Apotex extended to Janssen offers of confidential access to Apotex's ANDA No. 77-719.

V. The Present Suit And Janssen's Litigious Conduct And Aggressive Defense Of Its Risperidone Monopoly.

48. Janssen has a policy, practice, and history of vigorously enforcing its patents against generic drug applicants seeking to compete with Janssen, including risperidone ANDA applicants.

49. Janssen has filed numerous actions for patent infringement in the United States against generic companies seeking to market generic risperidone products in competition with Janssen's own Risperdal® product.

50. Janssen has demonstrated a willingness and intent to enforce its risperidone patents against generic pharmaceutical companies that have filed ANDAs to market generic risperidone.

51. On or about March 7, 2006, Janssen sued Apotex in this District alleging infringement of the '663 patent under 35 U.S.C. § 271(e)(2)(A).

52. On or about that same date, Janssen also sued Apotex in the United States District Court for the Northern District of Illinois, Eastern Division, alleging infringement of the '663 patent under 35 U.S.C. § 271(e)(2)(A).

53. To date, Janssen has filed at least five other actions for infringement of the '663 patent in this District against other ANDA applicants seeking to market generic risperidone

products, including Mylan Pharmaceuticals Inc., Dr. Reddy's Laboratories Ltd. and Barr Laboratories Inc.

54. Janssen also has not hesitated to sue numerous other ANDA applicants attempting to market competing generic versions of other Janssen brand products. For example, Janssen filed suit for patent infringement against at least seven generic ANDA applicants seeking to market generic versions of Janssen's Razadyne® (galantamine) product. Janssen also has filed actions against generic ANDA applicants seeking to market generic versions of Janssen's Sporanox®, Axert®, and Duragesic® brand products.

55. In sum, Janssen is, to say the least, a very litigious company that aggressively asserts its intellectual property rights against ANDA applicants seeking to market competing generic versions of Janssen's brand products.

56. As noted, Janssen already has sued Apotex for infringement of the '663 patent in two different Districts. Upon information and belief, Janssen also intends to assert the '425 and '587 patents against Apotex and its generic risperidone oral solution product.

57. By submitting the '663, '425, and '587 patents to FDA for listing in the Orange Book, Janssen has affirmatively represented to Apotex that "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1).

58. By preparing and filing an ANDA, Apotex has invested substantial sums and resources and substantially prepared to make, use, or sell generic risperidone oral solution in the United States.

59. By submitting its ANDA with a paragraph IV certification to engage in the commercial manufacture, use, or sale of generic risperidone oral solution before the expiration of

the ‘663, ‘425, and ‘587 patents, Apotex has committed a statutory act of infringement sufficient to create case or controversy jurisdiction under 35 U.S.C. § 271(e)(2)(A) and Article III of the Constitution.

60. Janssen has never communicated to Apotex that Apotex does not infringe or that Janssen does not intend to bring a lawsuit against Apotex for infringement of the ‘425 and ‘587 patents. Apotex thus faces enormous potential infringement liability if Apotex commences marketing before the ‘425 and ‘587 patents expire.

61. Apotex is under a reasonable apprehension that it will face suit for infringement of one or more of the ‘425 and ‘587 patents by manufacturing, using, selling, offering for sale or importing in the United States its generic risperidone oral solution product.

62. There is an actual, substantial, and continuing justiciable case or controversy between Janssen and Apotex regarding the infringement, validity and enforceability of the ‘663, ‘425, and ‘587 patents.

63. The MMA authorizes Apotex to file and maintain these counterclaims on the ‘425 and ‘587 patents. *See* 21 U.S.C. § 355(j)(5)(C)(i)(II); 35 U.S.C. § 271(e)(5).

COUNT I
(Declaratory Judgment of Non-Infringement of the ‘663 Patent)

64. Apotex repeats each of the foregoing paragraphs as if fully set forth herein.

65. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Janssen regarding the non-infringement of the ‘663 patent.

66. The manufacture, use, sale, offer for sale, or importation of the risperidone oral solution drug product that is the subject of Apotex’s ANDA No. 77-719 has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ‘663 patent.

67. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the risperidone oral solution drug product that is the subject of Apotex's ANDA No. 77-719 has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '663 patent.

COUNT II
(Declaratory Judgment of Invalidity of the '663 Patent)

68. Apotex repeats each of the foregoing paragraphs as if fully set forth herein.

69. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Janssen regarding the invalidity of the '663 patent.

70. The claims of the '663 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

71. Apotex is entitled to a judicial declaration that the claims of the '663 patent are invalid.

COUNT III
(Declaratory Judgment of Non-Infringement of the '425 Patent)

72. Apotex repeats each of the foregoing paragraphs as if fully set forth herein.

73. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Janssen regarding the non-infringement of the '425 patent.

74. The manufacture, use, sale, offer for sale, or importation of the risperidone oral solution drug product that is the subject of Apotex's ANDA No. 77-719 has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '425 patent.

75. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the risperidone oral solution drug product that is the subject of

Apotex's ANDA No. 77-719 has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '425 patent.

COUNT IV
(Declaratory Judgment of Non-Infringement of the '587 Patent)

76. Apotex repeats each of the foregoing paragraphs as if fully set forth herein.

77. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Janssen regarding the non-infringement of the '587 patent.

78. The manufacture, use, sale, offer for sale, or importation of the risperidone oral solution drug product that is the subject of Apotex's ANDA No. 77-719 has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '587 patent.

79. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the risperidone oral solution drug product that is the subject of Apotex's ANDA No. 77-719 has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '587 patent.

WHEREFORE, Apotex respectfully prays for judgment against Plaintiffs/Counterclaim-Defendants as follows:

(a) Declaring that the manufacture, use, sale, offer for sale, or importation of the risperidone oral solution drug product that is the subject of Apotex's ANDA No. 77-719 has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '663, '425, or '587 patent;

(b) Declaring that the claims of the '663 patent are invalid;

(c) Ordering that Plaintiffs/Counterclaim-Defendants' Complaint be dismissed with prejudice and judgment entered in favor of Apotex;

(e) Declaring this case exceptional and awarding Apotex its reasonable attorneys' fees and costs of these Counterclaims under 35 U.S.C. § 285; and

(f) Awarding Apotex such other and further relief as the Court may deem just and proper.

JURY DEMAND

Apotex hereby demands a trial by jury as to all issues so triable.

CARELLA, BYRNE, BAIN, GILFILLAN,
CECCHI, STEWART & OLSTEIN, PC
Attorneys for Defendant

Dated: April 25, 2006

By: /s/ James E. Cecchi
JAMES E. CECCHI [JC7697]

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